UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

FRANCIS X. JOYCE, and BELINDA JOYCE,	)	
Plaintiffs,	)	
v.	)	No. 4:15-CV-468 JAR
DAVOL, INC., and C. R. BARD, INC.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter is before the Court on Defendant C. R. Bard, Inc.'s Motion to Dismiss Plaintiffs' Complaint (Doc. No. 9) and Plaintiffs' Motion for Leave to Propound Discovery or, in the Alternative, Request for Scheduling Conference. (Doc. No. 25) The motions are fully briefed and ready for disposition.[1]

I. Background

This products liability personal injury action arises from a hernia surgery that took place in 2005. On March 13, 2015, Plaintiffs Francis and Belinda Joyce filed a Complaint against Defendants Davol, Inc. ("Davol") and C. R. Bard, Inc. ("Bard")[2] alleging that the defective condition of their mesh plug (Marlex Perfix Large lot # 43EDD126) used in inguinal hernia

[1] Bard filed an opposition to Plaintiffs' motion on October 27, 2015. (Doc. No. 26) Plaintiffs did not file a reply and the time for doing so has passed.

[2] Davol, Inc. is a Delaware company with its principal place of business in Rhode Island. C.R. Bard, Inc. is the New Jersey parent corporation of Davol, Inc. Thrope v. Davol, Inc., No. C.A. 008-463ML, 2011 WL 470613, at *2 (D. R.I. Feb. 4, 2011).

repairs, known as the "Bard PerFix Plug®," caused him to suffer "ongoing severe pain, atrophy, medical bills and missed work." (Complaint ("Compl."), Doc. No. 1)

Plaintiffs allege that on December 12, 2005, Plaintiff Francis Joyce underwent a surgical procedure to repair a right inguinal, or groin area, hernia, during which a PerFix Plug® was implanted. (Id. at Count I, ¶ 7) Plaintiffs further allege that over time, the mesh plug "created an inflammatory response in Mr. Joyce's body, entrapping nerves, eroding and sticking to nearby structures, and causing extreme pain, necessitating three separate surgeries on August 22, 2011, October 12, 2011, and January 3, 2012. (Id. at ¶ 10) In his first surgery of August 22, 2011, the surgeon found entrapment of the ilio-ingunal nerve in the mesh. (Id.) In the second surgery of October, 12, 2011, the surgeon found erosion of the mesh plug through the deep inguinal ring. (Id.) In the third surgery of January 3, 2012, the surgeon found residual mesh adhered in the medial aspect of the right groin, which he had to chisel out. (Id.) Plaintiffs allege that as a result of the mesh plug, Mr. Joyce incurred the pain and inconvenience of these surgeries, as well as the pain from the mesh entrapping, eroding and adhering to his nerves and structures. Plaintiffs further allege that Mr. Joyce will suffer from pain and atrophy into the future, and may require further medical care.

Plaintiffs assert claims for strict liability product defect (Count I), strict liability failure to warn (Count II), negligent manufacture,[3] design, and failure to warn (Count III), and spousal injury (Count IV). Bard moves to dismiss Plaintiffs' complaint for failure to state a claim upon which relief may be granted.[4]

[3] Plaintiffs have now abandoned their negligent manufacturing claim. (See Doc. No. 12 at 6) Accordingly, the Court will dismiss that claim with prejudice.

[4] Davol and Plaintiffs have stipulated that in exchange for Davol's waiver of service, Davol has thirty (30) days after the Court enters a ruling on Bard's motion to dismiss to respond to Plaintiffs' complaint. (Doc. No. 23)

II. Legal standard

In ruling on a motion dismiss under Rule 12(b)(6), the Court must view the allegations in the complaint in the light most favorable to Plaintiffs. Foster v. Deutsche Bank Nat. Trust Co., 2012 WL 5285887, 2 (E.D. Mo. Oct. 25, 2012) (citing Eckert v. Titan Tire Corp., 514 F.3d 801, 806 (8th Cir. 2008)). The Court "must accept the allegations contained in the complaint as true and draw all reasonable inferences in favor of the nonmoving party." Id. (quoting Coons v. Mineta, 410 F.3d 1036, 1039 (8th Cir. 2005)). The complaint's factual allegations must be sufficient "to raise a right to relief above the speculative level," however, and the motion to dismiss must be granted if the complaint does not contain "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 570 (2007) (abrogating the "no set of facts" standard for Fed. R. Civ. P. 12(b)(6) found in Conley v. Gibson, 355 U.S. 41, 45–46 (1957)). Thus, a dismissal under Rule 12(b)(6) should be granted "only in the unusual case in which a plaintiff includes allegations that show, on the face of the complaint, that there is some insuperable bar to relief." Strand v. Diversified Collection Serv., Inc., 380 F.3d 316, 317 (8th Cir. 2004). The issue on a motion to dismiss is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of his or her claim. Rosenberg v. Crandell, 56 F.3d 35, 37 (8th Cir.1995).

III. Discussion

A. Bard's motion to dismiss

Strict liability product defect (Count I) and Negligent product defect (Count III)

In support of its motion to dismiss, Bard first argues that Plaintiffs' strict liability product defect claim (Count I) is barred by Comment k to the Restatement (Second) of Torts, § 402A, which recognizes that prescription medical devices, such as the Bard PerFix Plug®, are

"unavoidably unsafe" products, for which claims for strict liability design defect are inappropriate. (Doc. No. 10 at 4-5; Doc. No. 14 at 2-4) (citing Racer v. Utterman, 629 S.W.2d 387, 393 (Mo. Ct. App. 1981) (finding a surgical drape to be an "unavoidably unsafe product" because of its flammable nature). The Restatement (Second) of Torts, § 402A, states in relevant part as follows:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

Restatement (Second) of Torts, § 402A(1). Comment k provides an exception to this rule, as follows:

> k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs … Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, ... many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician … The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use …

Restatement (Second) of Torts, § 402A Comment k.

Relying on Hill v. Searle Labs., a Div. of Searle Pharm., Inc., 884 F.2d 1064, 1068 (8th Cir. 1989) and Anastasi v. Wright Medical Technology, Inc., 16 F. Supp. 3d 1032, 1041 (E.D. Mo. 2014), Plaintiffs respond that the Eighth Circuit considers Comment k an affirmative defense to be proven by the defendant, and as such cannot be resolved on a motion to dismiss. (Doc. No. 12 at 5) Plaintiffs assert that Bard's reliance on Racer is misplaced because the case actually proceeded to trial and was submitted to a jury. (Doc. No. 12 at 6)

In Anastasi, a woman who received an allegedly defective hip implant brought a strict liability design defect claim against the manufacturers. The manufacturers moved to dismiss her claim, arguing she could not, as a matter of law, state such a claim pursuant to Comment k. 16 F. Supp. 3d at 1040. In her opposition to the motion to dismiss, Anastasi argued, *inter alia*, that Comment k is generally recognized as an affirmative defense, which would require the defendants to present proof the hip implant was incapable of being made safer at the time of manufacture and distribution. U.S. District Judge Webber found defendants' Comment k argument premature:

> Section 402A subjects to liability the seller or manufacturer of a product sold in a defective condition unreasonably dangerous to an ultimate user or consumer whose person or property is physically harmed by the product. The design defect claim's "unreasonably dangerous" inquiry involves a two-step analysis to evaluate the possible liability of a manufacturer for injuries caused by its inevitably hazardous product: 1) whether the product is so unsafe that marketing at all is "unreasonably dangerous per se"; and 2) if not, whether the product has been introduced into the stream of commerce with insufficient safeguards and is thereby "unreasonably dangerous as marketed." The first prong of the inquiry involves a balancing process in which the product's utility is weighed against the potential harmful effects caused by its introduction into commerce. Only if the product is determined not "unreasonably dangerous per se" does the analysis proceed to the "unreasonably dangerous as marketed" inquiry, at which point Comment k becomes applicable. Because the prerequisite "unreasonable dangerous" determination involves weighing of evidence, consideration of the applicability of Comment k's bar to [Anastasi's] strict liability design defect claim is not appropriate in a motion to dismiss.

Id. at 1041 (internal citations and quotation marks omitted). Likewise, Bard's Comment k argument is inapplicable at this juncture. The Court will deny Bard's motion to dismiss Count I (strict liability product defect) on this basis.

Next, Bard challenges the sufficiency of Plaintiffs' allegations of product defect under either a strict liability or negligent theory, arguing that Plaintiffs fail to identify a *specific* defect in the Bard PerFix Plug® or causal connection between any such defect and Mr. Joyce's alleged injuries. (Doc. No. 10 at 5-6) For example, as to strict liability, Plaintiffs allege the PerFix Plug®

was "in a defective condition unreasonably dangerous when put to a reasonably anticipated use," and that Plaintiff "was damaged as a direct result of the defective condition of the mesh plug as existed when the mesh was designed." (Compl., Count I at ¶¶ 8, 10) Bard complains these are boilerplate allegations that merely restate the legal standards for product defect without sufficient factual support. (Doc. No. 10 at 6)

In response, Plaintiffs assert their complaint clearly and specifically alleges the specific hazard of the mesh plug, i.e., its capability "of causing inflammation, entrapment, adherence and erosion of nearby structures" and that this hazard caused Plaintiff's injuries. (Doc. No. 12 at 4) Plaintiffs further allege that "the mesh plug over time created an inflammatory response in Plaintiff's body, entrapping nerves, eroding and sticking to nearby structures, and causing extreme pain, necessitating three separate surgeries." (Compl., Count I at ¶¶ 8, 10)

"A complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." Twombly, 550 U.S. at 555. After all, "Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief," in order to 'give the defendant . . . fair notice of what the . . . claim is and the grounds upon which it rests.' " Id. at 555 (citations omitted). All that is required of this short plain statement is that the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Id. at 570; see also Iqbal, 129 S. Ct. at 1950 (noting that the complaint must move from "conceivable to plausible"). Indeed, "it would be rare for a plaintiff at the time of the filing of a complaint to have more factual information than that alleged …, i.e., that the defendants designed, manufactured and marketed the specified product; that the [plaintiff] used the product properly for its intended use …; and that the product directly and proximately caused [an injury]." Turner v. Mylan, Inc., No. 4:09-CV-1816-TIA, 2010 WL 1608852, at *2 (E.D. Mo.

Apr. 20, 2010) (citing Houston v. Mylan, Inc., No. 8:09-CV-306 (D. Nev. Nov. 20, 2009)). Moreover, Bard is certainly aware of what defects the plug is alleged to have. See In re Kugel Mesh Hernia Patch Products Liability Litigation, MDL No. 1842, No. 07-MD-1842-ML (D.R.I.), involving claims surrounding allegedly defective hernia repair patches designed and manufactured by Defendants Davol and Bard. The Court will deny Bard's motion to dismiss Count I (strict liability product defect) and Count II (negligent product defect).

Strict liability failure to warn (Count II) and Negligent failure to warn (Count III)

In further support of its motion to dismiss, Bard argues that Plaintiffs fail to allege facts showing their failure to warn claims are not barred by the "learned intermediary" doctrine. (Doc. No. 10 at 6-7; Doc. No. 14 at 8) The learned intermediary doctrine provides that a manufacturer has a duty to warn a physician of the risks involved with its product. The physician then acts as a "learned intermediary" between the manufacturer and the patient so that any warning given to the physician is deemed a warning to the patient. Redd v. DePuy Orthopedics, 48 F. Supp.3d 1261, 1270-71 (E.D. Mo. Sept. 8, 2014) (citing Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671 (8th Cir. 1985); Doe v. Alpha Therapeutic Corp., 3 S.W. 3d 404, 419 (Mo. Ct. App. 1999)). Bard argues Plaintiffs fail to specify who Bard failed to warn and that to the extent Mr. Joyce is alleging that Bard failed to warn *him* of the alleged defect of the PerFix Plug®, his claims are contrary to Missouri law and must be dismissed. In addition, Bard argues that Plaintiffs fail to allege any facts regarding the labeling that accompanied the PerFix Plug®. (Doc. No. 10 at 7)

Plaintiffs respond that such allegations are not necessary to survive a motion to dismiss. (Doc. No. 12 at 6) In Redd, 48 F. Supp. 3d 1261, the district court noted that Missouri's learned intermediary doctrine is typically asserted as an affirmative defense to a failure to warn claim and that a plaintiff is not required to plead facts tending to negate it in order to survive a motion

to dismiss. Id. at 1271 n. 5 (citing Alpha Therapeutic Corp., 3 S.W. 3d. at 418-21; Stanger v. Smith & Nephew, Inc., 401 F. Supp. 2d 974, 984 (E.D. Mo. 2005); Wright v. American Home Products Corp., No. 06-CV-4183-NKL, 2008 WL 1820902 at *3 (W.D. Mo. Apr. 18, 2008)). See also Bohnenstiehl v. Wright Medical Group, Inc., No. 4:13-CV-853, at *3 (E.D. Mo. Jan. 29, 2014), where the district court denied defendant's motion to dismiss plaintiff's failure to warn claims despite defendant's argument that plaintiff was required to allege what warnings were given and how they were deficient. The Court will deny Bard's motion to dismiss Count II (strict liability failure to warn) and Count III (negligent failure to warn) on this basis.

Negligence claims (Count III)

Next, Bard argues Plaintiffs' negligence claims fail to plead facts showing how Bard breached any duty to Plaintiffs or how any such breach proximately caused Plaintiffs' injuries. (Doc. No. 10 at 9) Plaintiffs do not address this argument in their memorandum in opposition.

Under Missouri law, " '[i]n an action for negligence, generally, a plaintiff must allege ultimate facts which if proven, show: (1) the existence of a duty on the part of the defendant to protect the plaintiff from injury; (2) failure of the defendant to perform that duty; and (3) injury to the plaintiff resulting from such failure.' " Menz v. New Holland N. Am., Inc., 460 F. Supp. 2d 1058, 1067 (E.D. Mo. 2006) aff'd, 507 F.3d 1107 (8th Cir. 2007) (quoting Pro Service Automotive, L.L.C. v. Lenan Corp., 2005 WL 3371054 at *13 (W.D. Mo. Dec. 12, 2005)). Thus, to recover on a claim for negligent design or failure to warn, a plaintiff must establish that the defendant failed to use ordinary care to either design the product to be reasonably safe or adequately warn of the risk of harm from the alleged defect. Id. See also Stanley v. Cottrell, Inc., 784 F.3d 454, 463 (8th Cir. 2015) (citing Stevens v. Durbin–Durco, Inc., 377 S.W.2d 343, 347 (Mo.1964); Blevins v. Cushman Motors, 551 S.W.2d 602, 607-08 (Mo. 1977)).

Plaintiffs allege Defendants failed to use ordinary care to manufacture and design the PerFix Plug® to be reasonably safe so that it would not, over time, cause inflammation, entrapment, adherence, and erosion of nearby nerves and structures, and pain. Plaintiffs further allege Defendants failed to use ordinary care to adequately warn of the risk of harm from the mesh plug with reasonably anticipated use and that such failures directly caused or directly contributed to cause the damages alleged in Count I. (Compl., Count III at ¶¶ 4, 5) The Court finds these allegations satisfy the standard set forth in Twombly and Iqbal in that they raise a reasonable expectation that discovery will reveal evidence of Plaintiffs' negligence claim. Twombly, 550 U.S. at 556. The Court will therefore deny Bard's motion to dismiss Count III.

Spousal injury (Count IV)

In Count IV, Plaintiff Belinda Joyce alleges loss of consortium based on Mr. Joyce's alleged injuries. "[A] loss of consortium claim is wholly derivative, and thus rises or falls with the success of the underlying claims of the injured spouse." Menz, 460 F. Supp. 2d at 1067-68 (citing Wright v. Barr, 62 S.W.3d 509, 537 (Mo. Ct. App. 2001)). In light of the Court's ruling that Mr. Joyce's claims survive Bard's motion to dismiss, Mrs. Joyce's claims survive as well.

In sum, accepting the Complaint's well-pleaded allegations as true, and liberally construing it in Plaintiffs' favor, the Court finds Plaintiffs' Complaint alleges enough facts "to raise a right to relief above the speculative level …" Twombly, 550 U.S. at 555. Thus, the Court denies Bard's Motion to Dismiss, save Plaintiffs' negligent manufacturing claim in Count III.

B. Plaintiffs' Motion for Leave to Propound Discovery or, in the Alternative, Request for Scheduling Conference

In their motion, Plaintiffs seek leave from the Court to propound generalized interrogatories and requests for production on Bard to move the case forward. Alternatively, Plaintiffs request a scheduling conference. Bard opposes the motion, asserting it is premature to

conduct written discovery while its motion to dismiss is pending and before Davol files a responsive pleading. The Court has now ruled on Bard's motion to dismiss, and will set the case for a Rule 16 conference by separate order. Therefore, Plaintiffs' motion will be denied as moot.

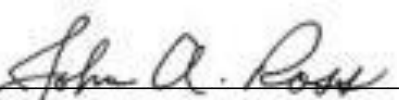
Accordingly,

IT IS HEREBY ORDERED that Defendant C. R. Bard, Inc.'s Motion to Dismiss Plaintiffs' Complaint [9] is **GRANTED** as to Count III (Negligent Manufacture). In all other respects, the motion is **DENIED**.

IT IS FURTHER ORDERED that Defendant Davol, Inc. shall respond to Plaintiffs' Complaint no later than **March 29, 2016**.

IT IS FURTHER ORDERED that because a Rule 16 conference will be set by separate order, Plaintiffs' Motion for Leave to Propound Discovery or, in the Alternative, Request for Scheduling Conference [25] is **DENIED** as moot.

Dated this 29th day of February, 2016.



JOHN A. ROSS
UNITED STATES DISTRICT JUDGE